Remarks/Arguments

I. Status of the Claims

Claims 1 -10, 12 – 50, 72 -75, 84, and 86 – 90 are currently pending. No claims are added, amended, or canceled with the filing of this paper.

II. Information Disclosure Statement

A second copy of the non-patent literature reference submitted 6/24/08 is enclosed with this paper.

III. Rejection under 35 U.S.C. § 112, second paragraph

Applicants respectfully disagree with the rejection of claims 16 and 29 under 35 U.S.C. § 112, second paragraph because the meanings of the trademark/trade names Celutab™, Rexcel™ and Stearowet™ were satisfactorily defined in the literature at the time the present application was filed.

As provided in MPEP 608.01(v)(emphasis added):

> Trademark: a word, letter, symbol, or device adopted by one manufacturer or merchant and used to identify and distinguish his or her product from those of others. It is a proprietary word, letter, symbol, or device pointing distinctly to the product of one producer.
>
> Names Used in Trade: a nonproprietary name by which an article or product is known and called among traders or workers in the art, although it may not be so known by the public, generally. Names used in trade do not point to the product of one producer, but they identify a single article or product irrespective of producer.
>
> Names used in trade are permissible in patent applications if: ...
>
> (B) In this country, their meanings are well-known and satisfactorily defined in the literature.

Attached hereto are pages from the reference, "Pharmaceutical Dosage Forms: Tablets Volume 1, 2nd Edition" on which the names Celutab™, Rexcel™ and Stearowet™ and

their respective meanings appear. As shown on the enclosed copyright page, this reference was published in 1989 which is before the filing date of the present application.

It is therefore respectfully submitted that use of the trade names Celutab™, Rexcel™ and Stearowet™ is permissible under MPEP 608.01(v) because these trade names were well-known and satisfactorily defined in the literature at the time the present application was filed.

In view of the above, reconsideration and withdrawal of the rejection is respectfully requested.

IV. Rejection under 35 U.S.C. § 103(a)

Claims 1 -10, 12- 75, 84 and 86-90 stand rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Franson et al. US 5,591,456 in view of Black, EP 0 863 134 and AAPS Annual Meeting Contributed Papers Abstracts.

A *prima facie* case of obviousness requires, *inter alia*, that the cited references teach or suggest every element of the claims. It is respectfully submitted that a *prima facie* case of obviousness has not been established because the cited references, either alone or in combination, fail to teach or suggest every element of the present claims. As such, the rejection is improper and should be withdrawn.

Specifically, the cited references fail to teach or suggest a composition comprising: (1) particulate celecoxib in an amount of about 10 mg to about 1000 mg in intimate mixture with one or more pharmaceutically acceptable excipients; and (2) having a distribution of celecoxib particle sizes such that D_{90} of the particles is less than 200 μm; and (3) said composition exhibiting upon oral administration a relative bioavailability not less than about 50% by comparison with an orally delivered solution containing celecoxib at the same dosage rate.

Franson (US 5,591,456)

Franson discloses particles consisting essentially of an NSAID having hydroxypropyl cellulose adsorbed on the surface thereof in an amount sufficient to maintain an average particle size of less than about 1000 nm. (Franson, Abstract, and Col. 2, lines 4 -11, emphasis added) Clearly, Franson teaches a composite particle – a composite particle comprised of an NSAID, such as naproxen, "having its surface modified with hydroxypropyl cellulose." (Franson, Col. 2, lines 44-47)

It is respectfully submitted that the composite particle taught in Franson is not the particulate celecoxib of the present claims.

The present claims are directed to, *inter alia*, particulate celecoxib having a distribution of celecoxib particle sizes such that D_{90} of the particles is less than 200 µm. (emphasis added) Franson neither teaches nor suggests the particulate celecoxib of the present claims at least because Franson teaches a composite particle consisting essentially of naproxen and hydroxypropyl cellulose. As discussed below, neither Black nor the AAPS reference cures this deficiency.

Applicants agree with the Examiner that Franson also fails to teach the other elements of the present claims. For example, on page 4 of the Action, the Examiner admits that Franson does not teach the compound of the present claims, celecoxib, and on page 5, the Examiner admits that Franson does not teach any of the claimed properties, such as bioavailability, C_{max} and/or T_{max}.

Black (EP 0 863 134)

Like Franson, Black does not teach the claimed compound celecoxib. Rather Black teaches a different COX-2 inhibitor and various compositions thereof. Nowhere does Black describe or suggest the composition of the present claims.

AAPS reference

The Office states on page 5 of the Action, that "AAPS teaches properties of a COX-2 formulation that are useful in the pharmaceutical arts."

The Office's reliance on the AAPS reference as teaching "a formulation" is misplaced for a number a reasons. First, the AAPS reference provides no teaching as to the nature of the suspension (is it an aqueous suspension? are there excipients and/or suspending agents present?). Second, besides disclosing that the capsules contained 300 mg of celecoxib, the AAPS reference fails to disclose any further information regarding this dosage form. Specifically, the AAPS reference fails to teach whether the celecoxib in the capsule was in the form of solid particles, in a suspension, or in solution; and whether the celecoxib in the capsule was formulated in any way, including whether there were excipients present and, if so, identifying those excipients. Finally, the AAPS reference is silent as to the particle size distribution of the celecoxib in either the suspension or the capsule. Accordingly, it is respectfully submitted that the AAPS reference fails to teach a formulation at all.

In determining the differences between the prior art and the claims, the question under 35 U.S.C. 103 is not whether the differences themselves would have been obvious, but whether the claimed invention as a whole would have been obvious. MPEP § 2141.02(I) citing Stratoflex, Inc. v. Aeroquip Corp., 713 F.2d 1530, 218 USPQ 871 (Fed. Cir. 1983); Schenck v. Nortron Corp., 713 F.2d 782, 218 USPQ 698 (Fed. Cir. 1983).

Rather than consider the claimed invention as a whole as is required, the Office has engaged in impermissible hindsight, piecing together teachings of the prior art using the Applicants' specification as a blueprint.

For all the foregoing reasons, Applicants respectfully submit that Franson, Black, and the AAPS reference, alone or in combination, fail to disclose or suggest every element of the present claims. As such, the Office has not made a *prima facie* showing of obviousness. The rejection of the pending claims is therefore improper and should be withdrawn.

V. Conclusion

Reconsideration and allowance of all pending claims is respectfully requested.

If the Examiner believes a telephonic interview with Applicant's representative would aid in the prosecution of this application, the Examiner is cordially invited to contact Applicant's representative at the below listed number.

Respectfully submitted,

Date: December 22, 2008

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